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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,100	08/22/2001	David B. Weiner	UPN-4099	2243

7590 11/06/2003

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EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/935,100	WEINER ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *01* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2001*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Restriction Requirement

35 U.S.C. § 121

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

a. Group I, claim(s) 1-3, drawn to **pharmaceutical compositions comprising Vpr** and **methods** and for **inducing undifferentiated cells** to **differentiate** through the administration of said compositions, classified in class 424, subclass 188.1, and class 435, subclass 7.23.

b. Group II, claim(s) 1-3, drawn to **pharmaceutical compositions comprising a transgene** encoding Vpr and **methods** and for **inducing undifferentiated cells** to **differentiate** through the administration of said compositions, classified in class 536, subclass 23.72, and class 435, subclass 7.23.

c. Group III, claim(s) 4 and 5, drawn to **pharmaceutical compositions comprising Vpr-induced redifferentiated tumor cells** and **methods** of **treatment** employing said cells, classified in class 435, subclasses 7.23 and 366.

d. Group IV, claim(s) 4 and 5, drawn to **pharmaceutical compositions comprising redifferentiated tumor cells** carrying a Vpr **transgene** and **methods** of **treatment** employing said cells, classified in class 435, subclasses 7.23 and 366, and class 536, subclass 23.72.

e. Group V, claim(s) 6 and 7, drawn to a **screening method** and kit to **identify compounds capable** of **abrogating** the **effects** of **Vpr** on **cellular differentiation**, classified in class 435, subclasses 5 and 7.23.

f. Group VI, claim(s) 8-11, drawn to **antiviral screening methods** and kits capable of **identifying compounds** that **inhibit Vpr binding** to the **Gag structural proteins**, classified in class 435, subclass 5, and class 424, subclasses 188.1 and 208.1.

g. Group VII, claim(s) 12 and 13, drawn to a **method** and kit for **identifying compounds capable** of **abrogating p24 aggregation**, classified in class 435, subclasses 5 and 7.1.

h. Group VIII, claim(s) 14, drawn to isolated Vpr-specific **antibodies**, classified in class 530, subclass 388.3.

i. Group IX, claim(s) 15 and 16, drawn to a **method** and kit for the **detection** of **HIV employing Vpr-specific antibodies**, classified in class 435, subclasses 5 and 7.1.

j. Group X, claim(s) 17, drawn to **eukaryotically produced Vpr**, classified in class 530, subclass 300, and class 435, subclass 69.1.

k. Group XI, claim(s) 18 and 19, drawn to a **method** and kit for the **detection** of **HIV employing Vpr**, classified in class 435, subclasses 5 and 7.1.

l. Group XII, claim(s) 20 and 21, drawn to **methods** for **enhancing** or **inhibiting retroviral propagation** through the **administration** of **Vpr**, classified in class 435, subclass 5, and class 424, subclass 188.1.

m. Group XIII, claim(s) 20 and 21, drawn to **methods** for **enhancing** or **inhibiting retroviral propagation** through the **administration** of a Vpr **transgene**, classified in class 435, subclass 5, and class 424, subclass 188.1.

n. Group XIV, claim(s) 22 and 23, drawn to **methods** of **treating macrophage disorders** through the **administration** of **Vpr**, classified in class 435, subclass 7.24, and class 424, subclass 188.1.

o. Group XV, claim(s) 22 and 23, drawn to **methods** of **treating macrophage disorders** through the **administration** of Vpr **transgene**, classified in class 435, subclass 7.24, and class 536, subclass 23.72.

p. Group XVI, claim(s) 24 and 25, drawn to **Vpr drug delivery compositions** and **methods employing particles comprising Vpr, p24**, and an **envelope glycoprotein**, classified in class 435, subclass 440.

q. Group XVII, claim(s) 26, 27, and 31 drawn to a **fusion protein** comprising Vpr and a heterologous segment, as well as, **particles** and **delivery methods** employing said fusion protein, classified in class 424, subclass 192.1, and class 435, subclass 69.1.

r. Group XVIII, claim(s) 28-30, drawn to **nucleic acids, expression vectors**, and **transformed host cells** that encode a fusion protein, classified in class 536, subclass 23.4, and class 435, subclass 69.7.

s. Group XIX, claim(s) 32 and 33, drawn to **pharmaceutical compositions** and **methods** of **treatment employing Vpr**, classified in class 424, subclasses 188.1 and 208.1.

t. Group XX, claim(s) 32 and 33, drawn to **pharmaceutical compositions** and **methods** of **treatment employing** Vpr-specific **antibodies**, classified in class 424, subclass 147.1.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions VIII, X, XVII, and XVIII are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the identified groups is directed toward a structurally and functionally different product (e.g., antibodies, viral proteins, fusion proteins, nucleic acids). Accordingly, each group is clearly directed toward independent and distinct subject matter.

4. Inventions I-VII, IX, XI-XVI, XIX, and XX are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, each of the identified groups is directed toward a different methodology (e.g., treatment of hyperproliferative disorders, treatment of cell loss, antitumor screening assay, antiviral screening assay, protein aggregation assay, detection methodologies, facilitation of retroviral propagation, treatment of macrophage disorders, and treatment of HIV infection) that employs structurally and functionally unrelated reagents (e.g., Vpr protein, Vpr transgene, tumor cells, anticancer agents, antiviral agents, and antibodies) and methodology steps. Accordingly, each group is clearly directed toward different inventive concepts.

5. Inventions VIII and IX/XX are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the Vpr-specific antibodies can

be employed in a number of materially different processes such as diagnostic assays and affinity purification protocols.

6. Inventions X and I/V/VI/XII/XI/XIX are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the Vpr protein can be employed in a number of disparate methodologies such as the generation of immunological reagents or cell differentiation assays.

7. Inventions XVII/XVIII and I-VII/IX/XI-XVI/XIX/XX are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the products of Groups XVII and XVIII are neither required nor utilized by any of the identified methodologies.

8. Inventions VIII and I-VII/XI-XVI/XIX are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the product of Group VIII is neither required nor utilized by the identified methodologies.

9. Inventions X and II-IV/VII/IX/XIII-XVI/XX are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes

of operation, different functions, or different effects (M.P.E.P. § 806.04 and § 808.01). In the instant case, the product of Group X is neither required nor utilized by the methodologies of the identified groups.

10. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and require separate searches, restriction for examination purposes as indicated is proper.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143). Applicant is also advised that the claims should be amended to reflect the election, where necessary.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(I).

13. Applicants are reminded that a restriction between product and process claims has been set forth *supra*. When applicant elects claims directed to the product, and a product claim is subsequently found to be allowable, withdrawn process claims that depend from or otherwise include **all** the limitations of the allowable product claim will be rejoined in accordance with the provisions of § 821.04 of the M.P.E.P. Process claims that depend from or

otherwise include **all** the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. § 1.116 while amendments submitted after allowance are governed by 37 C.F.R. § 1.312.

14. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. § 1.104. Thus, to be allowable, the rejoined claims **must** meet all criteria for patentability as set forth under 35 U.S.C. §s 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. **Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.** See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer*, and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so will result in a loss of the right to rejoinder.** Furthermore, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. § 804.01.

Correspondence

15. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward the following Group 1600 fax number: (703) 872-9306. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (703) 308-1122 or (703) 308-4027, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

03 November, 2003